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### Authors

Carr, Andrew N  
DeWitt, Thomas  
Cork, Michael J  
et al.

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# Diaper dermatitis prevalence and severity: Global perspective on the impact of caregiver behavior

Andrew N. Carr PhD<sup>1</sup>  | Thomas DeWitt MD<sup>2</sup> | Michael J. Cork MB, PhD<sup>3</sup> | Lawrence F. Eichenfield MD<sup>4</sup>  | Regina Fölster-Holst MD<sup>5</sup> | Daniel Hohl MD<sup>6</sup> | Alfred T. Lane MD<sup>7</sup> | Amy Paller MD<sup>8,9</sup> | Larry Pickering MD<sup>10</sup> | Alain Taieb MD<sup>11</sup>  | Tao Y. Cui MD<sup>12</sup> | Zi G. Xu MD<sup>13</sup>  | Xueimin Wang MD<sup>14†</sup> | Susanna Brink PhD<sup>15</sup> | Yeqing Niu MD<sup>16</sup> | Julie Ogle BM, MT<sup>1\*</sup> | Mauricio Odio PhD<sup>1\*</sup> | Roger D. Gibb PhD<sup>1</sup>

<sup>1</sup>Procter & Gamble, Cincinnati, OH, USA

<sup>2</sup>Cincinnati Children's Hospital Medical Center, Cincinnati, OH, USA

<sup>3</sup>Sheffield Children's Hospital and University of Sheffield, Sheffield, UK

<sup>4</sup>Rady Children's Hospital, San Diego, CA, USA

<sup>5</sup>University of Schleswig-Holstein, Kiel, Germany

<sup>6</sup>Beaumont Hospital, CHUV-UNIL, Lausanne, Switzerland

<sup>7</sup>Stanford University School of Medicine, Stanford, CA, USA

<sup>8</sup>Northwestern University Feinberg School of Medicine, Evanston, IL, USA

<sup>9</sup>Ann and Robert H. Lurie Children's Hospital, Chicago, IL, USA

<sup>10</sup>Emory University School of Medicine, Atlanta, GA, USA

<sup>11</sup>Centre Hospitalier Universitaire de Bordeaux, Bordeaux, France

<sup>12</sup>Beijing United Family Hospital and Clinics, Beijing, China

<sup>13</sup>Beijing Children's Hospital, Capital Medical University, Beijing, China

<sup>14</sup>Shanghai Skin Disease Hospital, Shanghai, China

<sup>15</sup>Procter & Gamble, Schwalbach, Germany

<sup>16</sup>Procter & Gamble, Beijing, China

## Correspondence

Andrew N. Carr, PhD, Procter & Gamble Company, 6280 Center Hill Ave, Cincinnati, OH 45232.

Email: carr.an@pg.com

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## Abstract

**Objectives:** To compare prevalence and severity of diaper dermatitis (DD) in infants and toddlers (babies) across three countries (China, USA, and Germany), including diapered skin measures and caregiver practices.

**Methods:** A cross-sectional study of 1791 babies (~600 from each country) was recruited at each clinical site. Based on regional toilet-training habits, exclusively diaper-wearing infants were recruited between ages 2-8 months in China and 2-18 months in the USA and Germany. DD was measured, as well as skin pH, transepidermal water loss (TEWL), and relative humidity (RH) in the diapered region. Caregiver habits were collected via a questionnaire and included information on hygienic practices.

\*Retired.

†Deceased.

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**Results:** Diaper dermatitis was highest in the perianal area, followed by the intertriginous, genital, and buttock regions. In general, DD was significantly lower in babies in China, highest in Germany, and intermediate in the USA. This rank ordering of DD by geography was also observed in baby age 2-8 months. The lower DD observed in China was associated with lower skin pH and TEWL on diapered skin and decreased RH in the diaper. Chinese caregivers had the highest rate of prophylactic topical product usage, the most robust cleaning of the diapered area, lack of cleansing after urine-only diaper changes, and Chinese infants spent the least time in an overnight diaper.

**Conclusions:** These data suggest caregiver behaviors including prophylactic use of topical products, thorough cleaning after stooling and reduced time in an overnight diaper are associated with less DD, lower superficial skin pH, and enhanced skin barrier.

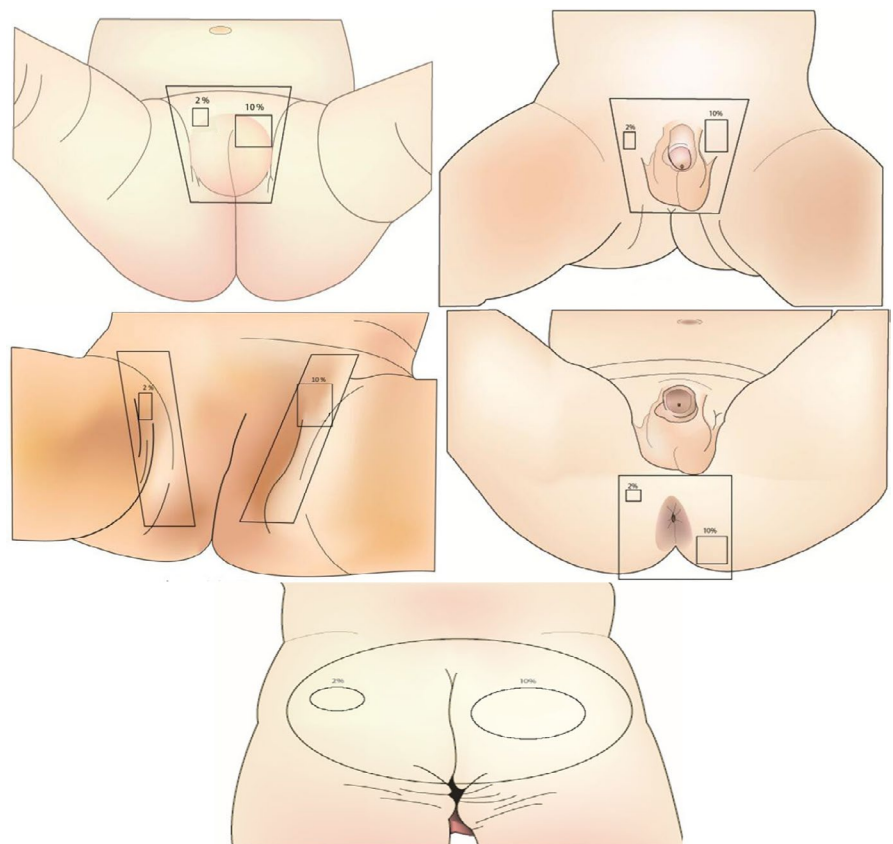
#### KEYWORDS

diaper dermatitis, neonatal, skin barrier

## 1 | INTRODUCTION

Diaper dermatitis (DD) is an acute, episodic inflammatory condition characterized by erythema, papules, and pustules in the diapered area. While common, DD is rarely serious from a medical standpoint, but can cause discomfort for infants and anxiety for caregivers.<sup>1-3</sup> Literature estimates of DD rates vary greatly, ranging from 16% to 65%, and given the short duration of DD (typically 2-4 days), most cases are not seen by a medical professional.<sup>3-6</sup>

Diaper dermatitis has many causes, including skin overhydration, friction, frequent, and prolonged exposure to urine or feces (which contain pH-sensitive proteases and lipases), and associated elevated skin pH and alterations in the skin microbiome.<sup>7-11</sup> Diaper dermatitis can be superimposed on or mistaken for other skin disorders with impaired barrier function including psoriasis and atopic dermatitis, the diapered skin typically being spared in the latter.<sup>12</sup> Protecting diapered skin entails reducing overhydration from urine or high humidity, maintaining skin's normal acidic pH, and minimizing contact



**FIGURE 1** Diagram for scoring diaper dermatitis. The anatomic area of skin scoring is defined by the large black box/circle in each image. Two smaller reference shapes within the scoring area are approximately 2% or 10% of the total area covered. Images from left to right and top to bottom are female genitals; male genitals; intertriginous; perianal; buttocks

with feces and urine.<sup>11</sup> To achieve this, strategies include using highly absorbent disposable diapers, frequent diaper changes, cleaning stool from skin with water or optimally formulated baby wipes, and emollient application.<sup>6,13-15</sup> While common, the direct impact of these strategies is not well understood.

Previous investigations on DD are derived from hospital admissions or doctor office visits, which are unlikely to reflect real-world settings, and do not consistently report the anatomic location or severity. In the present investigation, we studied DD experienced from three disparate geographies, each with different approaches to diapering habits and skin care.

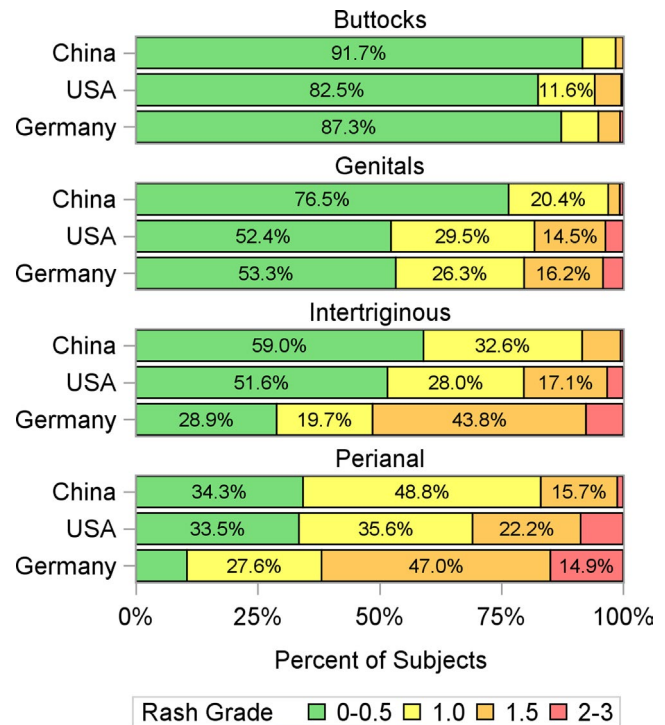
## 2 | SUBJECTS AND METHODS

In this cross-sectional study, babies were recruited at each clinical site (Beijing Health Tech Research Co. Ltd, Xi'an, China, 1 site; proDerm, Hamburg, Germany, 3 sites; North Cliff Consultants, Cincinnati, Ohio, 1 site). Investigators managed the study at each of their respective sites, conducting all procedures according to Good Clinical Practices. IRB/Ethics Board approval was obtained in each country. Informed consent was provided in the native language.

A total of 1791 babies participated in the study. Eligibility included baby ages 2-8 months in China and 2-18 months in the USA and Germany who were full-time diaper wearers. Babies were not recruited beyond 8 months in China due to early toilet training in that country. Babies were excluded if they had psoriasis, ichthyosis, varicella, or significant skin eruption in the diaper area, were taking systemic or topical medication for a chronic medical condition, or were currently experiencing or had a history of a chronic, serious disease (eg, epidermolysis bullosa, cancer, organ failure).

Diaper dermatitis was assessed at four distinct anatomic sites using a validated grader scoring tool: buttock (visible when baby is prone), genital, intertriginous (leg folds/creases), and perianal (along anal groove, not visible when baby is prone; Figure 1).<sup>16,17</sup> The skin grader (experienced in clinical research) characterized each of four skin attributes independently: presence/intensity of erythema, percent of area with erythema, number of papules, and number of pustules. The DD scale, accessed via a digital platform, allowed graders to enter values for each attribute separately, after which the DD value (7 point; 0-3 scale) was calculated using an integration algorithm. To ensure comparability, all graders completed the same DD training in their native language, which included demonstrating proficiency in scoring DD using a training set of photographs as well as completing 100 assessments from babies with varying levels of DD.

For temperature and relative humidity (RH) measures, babies were acclimated to room conditions  $\geq 30$  minutes before measures were taken. RH was measured using a thermohygrometer (Sato Keiryoki MFG. Co., LTD) covered with a breathable sleeve, allowing air exchange and preventing inadvertent sensor contact with liquid. Simultaneously, two thermohygrometer sensors were inserted into



**FIGURE 2** DD distribution assessed for babies 2-8 months. DD scores are reported for "mild" (score 1.0) and "mild-to-moderate" (score 1.5) individually, while scores for "none" (score 0) and "slight" (score 0.5) were combined, as were scores of "moderate" or greater severity (scores of 2.0, 2.5, 3.0)

the diaper, near the genitals and along the anal groove. Values were taken after 2 minutes of stable readings. If the baby had a soiled diaper, the baby was rediapered for  $\geq 30$  minutes before measures were collected. Transepidermal water loss (TEWL) was measured using a VapoMeter (Delfin Technologies, Ltd., Finland) after diaper removal and DD scoring, allowing superficial skin wetness to evaporate prior to measurement. TEWL values were measured on the thigh (control) and in the upper left quadrant of the genitals, avoiding areas of visible skin breakdown. Skin pH was measured using a SkinCheck portable pH meter (Hanna Instruments), and measures were taken on the thigh and upper right quadrant of the genitals to avoid any impact on TEWL measures. Caregivers detailed diapering hygiene practices and skin care treatments via a questionnaire administered onsite, reporting typical behaviors during the previous two weeks.

Demographics, diet, skin cleaning and bathing, topical skin product usage, and diaper hygiene habit data, as well as the relative distribution of DD scores, were summarized with descriptive statistics by country. Genital TEWL data were normalized by subtracting non-diapered thigh scores. It has been observed that TEWL measurements from babies who are agitated and sweating are unreliable.<sup>18</sup> Thus, infants in the study who had high thigh TEWL scores (the reference site;  $>23 \text{ g/m}^2/\text{hour}$ ) were excluded from the analysis, resulting in an exclusion of 9% of TEWL measurements for baby ages 2-8 months. Analysis of variance was used to statistically compare the mean levels of TEWL, pH, and RH between countries.

**TABLE 1** Demographics of baby ages 2-8 months

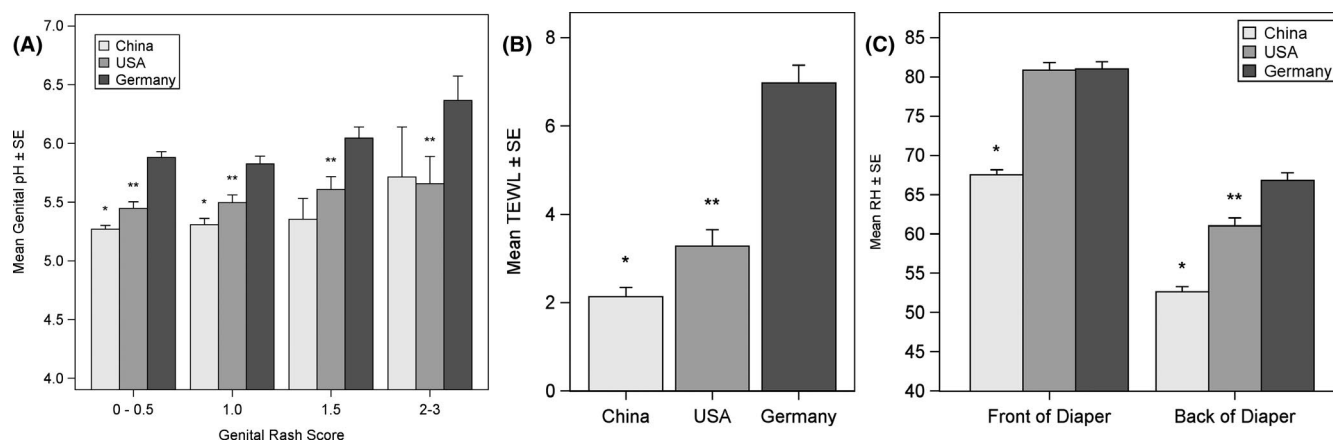
Demographic measures/Statistic	China (N = 591)	Germany (N = 316)	USA (N = 276)
Sex			
Female	272 (46.0%)	152 (48.1%)	133 (48.2%)
Male	319 (54.0%)	164 (51.9%)	143 (51.8%)
Age (Months)			
Mean (SD)	4.4 (1.78)	5.4 (1.89)	5.4 (1.91)
Median	4.0	5.0	5.5
Min-Max	2.0-8.0	2.0-8.0	2.0-8.0
Birthweight (kg)			
Mean (SD)	3.3 (0.52)	3.4 (0.59)	3.4 (0.54)
Median	3.3	3.4	3.4
Min-Max	1.3-4.6	0.3-5.1	1.0-4.9
Body weight (kg)			
Mean (SD)	8.0 (1.40)	8.0 (1.31)	7.8 (1.27)
Median	7.9	8.1	7.7
Min-Max	4.3-12.2	3.8-11.0	4.7-10.6
Gestational age (Weeks)			
Mean (SD)	38.9 (1.69)	39.3 (2.13)	39.0 (1.88)
Median	39.0	40.0	39.0
Min-Max	29.0-42.0	24.0-42.0	28.0-42.0
Race			
Asian Indian	0 (0.0%)	4 (1.3%)	0 (0.0%)
Asian Oriental	591 (100%)	19 (6.0%)	1 (0.4%)
Black	0 (0.0%)	16 (5.1%)	43 (15.6%)
Caucasian	0 (0.0%)	245 (77.5%)	186 (67.4%)
Multi-Racial	0 (0.0%)	31 (9.8%)	46 (16.7%)
Native Hawaiian or Pacific Islander	0 (0.0%)	1 (0.3%)	0 (0.0%)
Fitzpatrick skin type			
I	0 (0.0%)	13 (4.1%)	11 (4.0%)
II	0 (0.0%)	134 (42.4%)	69 (25.1%)
III	477 (80.7%)	114 (36.1%)	95 (34.5%)
IV	114 (19.3%)	38 (12.0%)	66 (24.0%)
V	0 (0.0%)	11 (3.5%)	29 (10.5%)
VI	0 (0.0%)	6 (1.9%)	5 (1.8%)

### 3 | RESULTS

By study design, there were differences in age, weight, race, ethnicity, and Fitzpatrick skin type between countries, but babies were otherwise similar in regard to sex, birthweight, and gestational age at birth. DD scoring across all study participants revealed the perianal region had the highest DD frequency and severity, followed by the intertriginous, genital, and buttock regions.

Comparisons across geographies were also conducted on a subgroup of baby age 2-8 months (Figure 2; Table 1) (China: n = 591; Germany: n = 316; USA: n = 276). Geographical differences in DD prevalence and severity observed in the overall population were mirrored in the 2-8 months of subgroup. All subsequent comparisons

were restricted to babies 2-8 months to eliminate the confounding factor of age. In babies 2-8 months of age, DD scored as moderate or greater severity (eg, a score of  $\geq 2.0$ ) was relatively infrequent, occurring in just 1.3% of babies in China, 8.7% in the USA, and 14.9% in Germany. One instance of *Candida* was noted in a baby from Germany in the setting of mild DD. All babies age 2-8 months old in China were on an exclusive milk diet compared to 29.5% in the USA and 26.3% in Germany. The predominant source of milk was of human origin (China: 75.7%; USA: 50.6%; Germany: 65.1%). An analysis of diaper rash by race and Fitzpatrick skin type indicated higher levels of rash in lighter skin individuals or Caucasians compared to darker skin babies or Blacks. When considering only Fitzpatrick skin types III and IV, the geographical differences in DD



**FIGURE 3** Diapered skin pH, TEWL, and RH in babies 2-8 months. A, Skin pH and DD severity. \* $P < .03$  vs USA, Germany. \*\* $P < .03$  vs Germany. B, TEWL from diapered skin \* $P < .01$  vs USA, Germany. \*\* $P < .01$  vs Germany. C, RH in diaper. \* $P < .0001$  vs USA, Germany. \*\* $P < .0001$  vs Germany

prevalence and severity noted in the overall population remained (data not shown).

### 3.1 | Diapered skin and environment measures

Skin pH was measured on diapered (genitals) and non-diapered (thigh) skin. The mean skin pH measures at both anatomic sites were lowest in China and highest in Germany. All pairwise comparisons of three countries were statistically significant ( $P < .05$ ). Higher skin pH was associated with more severe DD (Figure 3A). Diapered skin mean TEWL was significantly lower for babies in China, intermediate in the USA, and highest in Germany (Figure 3B). Mean RH in the diaper was higher near the site of urination than in the back of the diaper. For both sites, the mean RH was the lowest for Chinese babies vs USA/Germany (Figure 3C). Babies in the USA had intermediate RH in the back of the diaper ( $P < .05$  vs China and Germany), while no difference was found in the front of the diaper compared to German babies.

### 3.2 | Caregiver Habits Across Geographies

Disposable diaper use was similar across geographies (China 92.2%; USA 98.5%; Germany 100%), and a high percentage (>70%) of caregivers reported using  $\geq 1$  topical product during each diaper change "sometimes" or "all the time," across geographies. Continuous topical product use was highest in China (27.5%), followed by Germany (12.4%) and the USA (8.4%). Barrier creams and ointments (eg, semi-solid, Desitin® ointment, Eucerin® cream) were the predominant topical products of choice, regardless of geography (China: 54.5%, USA: 62.9%, Germany: 69.7%). The use of powders, oils, and lotions in the diaper area varied by country. (Powders: China 35%; USA 25.5%; Germany 8.9%. Lotion: China 4.9%; USA 17.5%; Germany 13.4%. Oils: China 8.7%; USA 3.6%; Germany 17.5%).

Assessment of caregiver practices indicated the typical number of diaper changes during a 24-hour period was highest in the USA

(mean  $\pm$  SD =  $7.9 \pm 2.44$  changes), followed by Germany ( $6.9 \pm 1.87$ ) and China ( $6.3 \pm 2.38$ ). Chinese infants spent the shortest period in the same diaper at night (on average  $\pm$  SD =  $6.0 \pm 2.27$  hours), followed by the USA ( $7.9 \pm 2.56$  hours) and Germany ( $8.5 \pm 2.92$  hours).

### 3.3 | Caregiver diaper hygiene practices

Many Chinese caregivers reported no skin cleaning (46.3%) for a urine-only diaper change, with 28.2% using a baby wipe and 13.4% using water. In the USA, for a urine-only diaper, wipes were used most frequently (83.9%), followed by no skin cleaning (8.4%) and cleaning with the diaper, for example, using dry portion of diaper to absorb urine (5.8%). German caregivers primarily used wipes (68.5%), followed by damp cloth (21.0%) or no skin cleaning (6.4%). For diapers containing stool, most caregivers in China (70.6%) reported an extensive skin cleaning routine utilizing water with or without soap (can include a water basin), baby wipes, and/or toilet tissues, with a quarter of parents (23.4%) using only baby wipes. In the USA, wipes were used most frequently (94.9%). German caregivers used wipes 74.5% of the time, while 21.3% reported using wash-cloth and water. Caregivers in the USA reported bathing the children the most frequently (56.9% bathed the child every other day), followed by Germany (39.5% bathed the child two times per week) and China (42.3% bathed the child once per week).

## 4 | DISCUSSION

This study assessed DD prevalence and severity in representative countries of Asia, North America, and Europe utilizing a DD scoring tool taking into account four skin attributes at four anatomic sites. The rank ordering of DD prevalence and severity between countries (China<USA<Germany) parallels the measures of diapered skin pH and TEWL (measures are lowest in the Chinese cohort), the latter being a measure of skin barrier integrity. Healthy skin exhibits an

acidic superficial pH, and the association of lower diapered skin pH and less severe DD observed here is consistent with previous findings.<sup>19,20</sup> These data signal the importance of maintaining an acidic environment for diapered skin to prevent or reduce DD severity.<sup>20</sup> Lower skin pH is associated with improved structural integrity of the stratum corneum, reduced propensity to activate fecal enzymes at the stool-skin interface, and growth of a more commensal microbiome community with suppression of pathogenic microorganisms, all of which are relevant to preventing DD.<sup>19-23</sup>

Our study demonstrated that the RH under the diaper was significantly lower for infants from China and the USA (perianal) compared with Germany. Higher RH in the diapered area may increase the risk of skin overhydration and could also impact microbiome diversity. This is consistent with previous research showing that diapers that maintain a lower humidity environment were associated with lower *Candida albicans* infection, a common contributor to DD.<sup>24</sup>

While other factors may explain differences in DD prevalence and severity across regions, caregiver behaviors are likely a contributor. The rank order of DD severity across geographies was associated with less time spent in the same diaper overnight, greater prophylactic topical product use, and a robust cleaning routine after a stooling event. While not measured here, it is noteworthy that Chinese caregivers commonly leave the infant undiapered for periods of time, which may prevent skin overhydration. Chinese infants may also have greater individualized care, due to the common practice of numerous family members providing care for a single child. This could explain why Chinese caregivers changed the diaper more frequently during the night, and coupled with higher prophylactic topical product use, would reduce skin exposure to fecal irritants. Reported bathing frequency did not follow the rash rank order, with more frequent bathing reported in the USA and least in China. However, it should be noted that a common practice in China involves robust cleaning after stooling events in a water basin or sink. This practice would account for 2 "baths" per day based on stooling patterns.

Topical products are widely recommended for DD, and use was reported by >70% of caregivers in this study. Prophylactic use was highest in China, but similar between the USA and Germany. While it is likely that prophylactic topical products were used to suppress rash, occasional use is difficult to interpret, since these products can also be used as medical treatments. The advantage of prophylactic cream/ointment use is supported by a reduction in DD in infants wearing diapers containing emollients with or without zinc oxide.<sup>16,17</sup>

Of the geographies studied, the USA and Germany had the most similar habits and practices. Lower DD observed in the USA compared with Germany was associated with higher packaged wipes usage, more frequent overnight diaper changes, and greater bathing frequency. These practices are consistent with current USA and European physician-led organization recommendations: using superabsorbent breathable diapers, frequent diaper changes, and gentle, mildly acidic wipes or water for cleansing.<sup>25-27</sup>

This study provides important insights on DD prevalence and severity and the impact of caregiver behaviors on DD. The finding that infants with more pigmented skin were scored as having less

severe rash is an interesting finding and requires further investigation. Techniques to reduce DD include the use of barrier creams to help protect skin from overhydration and contact with fecal irritants. The association of a lower frequency of DD with lower skin pH supports the use of mildly acidic cleaning products (eg, specially formulated baby wipes and soaps) to help maintain the skin's acid mantle and reduce the risk of skin damage by fecal enzymes which are more active at neutral or alkaline pH. The finding that DD is more frequently located in the perianal and intertriginous areas indicates caregivers should pay particular attention to these areas. There may be less airflow through these areas resulting in a moister environment, and it may be more difficult to clean these areas; these sites may benefit the most from prophylactic topical product use. Collectively, these results provide important insights into approaches to reduce DD severity and improve babies' health and well-being.

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## CONFLICT OF INTEREST

Andrew N. Carr, Susanna Brink, Yueqing Niu, and Roger D. Gibb are full-time employees at Procter & Gamble. Mauricio Odio and Julie Ogle are retired from Procter & Gamble. All authors acknowledge that this study was wholly funded by the Procter & Gamble Company.

## ORCID

Andrew N. Carr  <https://orcid.org/0000-0003-1676-8033>

Lawrence F. Eichenfield  <https://orcid.org/0000-0002-2760-0474>

Alain Taieb  <https://orcid.org/0000-0002-0928-8608>

Zi G. Xu  <https://orcid.org/0000-0001-8645-1854>

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